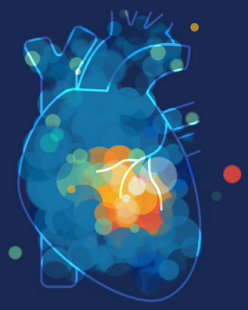
Case Study:

STRATEGIES FOR ACCELERATED ENROLLMENT AND FDA APPROVAL OF A PAF TREATMENT DEVICE



An innovative biotech partnered with Medpace to support its development efforts in conducting a trial to evaluate the safety and efficacy of a device intended to treat patients with drug-resistant, recurrent, symptomatic paroxysmal atrial fibrillation (PAF).

The following case study outlines strategies that Medpace took to accelerate the enrollment timeline and maintain patient compliance, contributing to successful study execution and subsequent FDA approval.

METRICS

30
SITES
all in the United States

741
PATIENTS SCREENED

706
PATIENTS ENROLLED
80 roll-in subjects + 626 randomized subjects

CHALLENGES

Meeting the specific deadlines for patient enrollment demanded an expedited and streamlined recruitment approach. A well-defined and thoroughly vetted strategy was essential to achieve the 15-month enrollment goals on time.

Study participants needed cardiac imaging to assess pulmonary vein dimensions, along with weekly event monitoring and 72-hour Holter monitoring throughout the trial. A robust patient retention strategy was necessary to ensure compliance and maintain accurate data collection.

SERVICES PROVIDED

The Sponsor leveraged Medpace's full-service outsourcing model to deliver quality results in a timely and efficient manner. Medpace services integrated into this trial included Clinical Monitoring, Data Management, Clinical Safety, Vendor Management, Quality Assurance, ClinTrak IRT, and the Medpace Imaging Core Lab.

RESULTS

- Received FDA approval as a unique new alternative to standard-of-care thermal ablation treatment
- Medpace activated all sites and completed patient enrollment within the projected timeline
- **81.6%** Event Monitor Compliance (MITT Subjects)
- **79.8%** 72-Hour Holter Compliance (12-Months, MITT Subjects)
- **90.4%** ECG Compliance (12-Months, MITT Subjects)
- **98.6%** 12-Month Visit Retention

THE SOLUTIONS

Site and Vendor Education: Formal guidance was provided to external sites and laboratory staff on tracking and managing data to ensure compliance, enhance efficacy, and minimize delays. A thorough analysis of SOPs and processes added an additional layer of oversight into study metrics, enabling the proper setting of expectations and timelines.

Patient Recruitment and Retention: By leveraging our ExcelliPACE® process – a platform for successful patient recruitment and retention – we effectively applied patient engagement strategies to maintain high retention rates in this study. At key milestones, financial incentives were introduced to encourage patient compliance, resulting in over 90% ECG compliance over a 12-month period. This approach also helped meet the industry standards of 80% for Event Monitor compliance and 72-hour Holter compliance. Medpace employed advanced patient payment methods to deliver timely payments, eliminate delays and manual processes, and navigate global regulations effectively.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective. If you have an upcoming trial that needs seamless execution, contact Medpace to learn more.

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